

REMARKS

The Final Office Action sent August 19, 2009 has been received and reviewed. All claims stand rejected. The claims are to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Support for the amendments may be found throughout the as-filed Specification, for example, in least at page 4, lines 7-25 and the claims as previously presented. No new matter has been presented. Reconsideration is respectfully requested.

35 U.S.C. § 102

Claims 1-5, 11-12, and 20 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent 5,189,053 to Willis et al. (“Willis”). Applicants respectfully traverse the rejection.

Unless a single prior art reference describes “all of the limitations claimed” and “all of the elements [are] arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIN Inc. v. VeriSign Inc.*, No. 07-1565, slip op. at 17-18 (Fed. Cir. Oct. 20, 2008). A single prior art reference must “clearly and unequivocally” describe the claimed invention “without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Id.* at 19 (citing *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)).

Applicants submit that claims 1-5, 11-12, and 20 are not anticipated by Willis, as Willis does not expressly or inherently disclose all of the elements of the claims. For example, as set forth in the Response submitted June 1, 2009, which remarks are incorporated by reference herein, Willis does not describe “administering a haloarylpyrazole to an animal prior to exposure of the animal to ticks.”

The Office asserts that the feature upon which applicants previously relied was not recited in the rejected claims. Claim 20, however, specifically recites a method for deterring ticks from infesting an uninfested animal comprising administering a haloarylpyrazole to the uninfested animal. Be that as it may, the claims have been amended to recite administering a haloarylpyrazole to an animal prior to exposure of the animal to ticks.

Applicants submit that claims 1-5, 11-12, and 20 are not anticipated by Willis at the very least because Willis does not disclose all the elements the claims, *e.g.*, administering a haloarylpyrazole to an animal prior to exposure of the animal to ticks. Reconsideration and withdrawal of the 35 U.S.C. § 102 rejections are respectfully requested.

Claims 1-5, 11-12, and 20 are additionally not anticipated by Willis, as Willis does not disclose “deterring” ticks from infesting the animal, as presently claimed. As set forth in the Response submitted June 1, 2009, Willis describes using the compounds of Formula I in order to combat active tick infestations. *Willis*, col. 3, lines 1-3, col. 28, lines 28-56. The examples of Willis merely show that the compound of Formula I may be used to kill ticks.

The Office alleges that Specification does not define the term “deterring.” Applicants respectfully disagree and note that “deterring” is clearly defined and described by the Specification as the claimed method’s ability to repel ticks and prevent them from biting and engorging. The Specification does not describe killing ticks. For example, the as-filed Specification states:

“[r]epellents and deterrents have the task of deterring harmful or troublesome arthropods from contacting, stinging or feeding on areas that are attractive to them, such as the skin of animals. It is the object of the current invention that this repellent effect can be reached by means of prior administration of the arylpyrazole compound to the host animals. The deterrent effect after administration of the compound results in anti-attachment and anti-feeding of the parasites, especially ticks. The deterrent (repellent) effect according to the current invention is shown in the example. A significant higher number of live, non-engorged ticks were found in the pens of dogs treated with a compound according to the invention compared to the environment of the control group.”

As-filed Specification, page 6, lines 6-16, emphasis added.

Thus, the Specification recites that the “deterrent (repellent) effect” according to the current invention is shown, *inter alia*, in the example. Thus, the Specification clearly defines the “deterring” or the “deterrent effect” as recited in the claims (the current invention) in terms of the Specification’s example, which does not involve killing the parasites.

As can be seen in the Specification’s example, “deterrent effect” was calculated and/or defined in terms of live, non engorged ticks. The example of the Specification describes a study wherein the number of live, unattached ticks were collected from pens of both groups were

statistically compared to determine a repellent/deterrent effect. *Id.* at 9, lines 16-20. After each day of testing (e.g., Day +2, Day +7, Day +14, etc.) the numbers of live, free ticks were collected and repellence was calculated and analyzed. *Id.* at page 9-10. The example's lack of any regard to dead ticks at the very least suggests that the Specification's example does not define "deterrent" as killing.

Applicants note that "the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification." MPEP § 2111.03 citing *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Applicants submit that in view of the description of "deterring" in the Specification, it would be inconsistent with the Specification to define "deterring" to necessarily include killing ticks.

Furthermore, even if "deterring" were to be construed according to such "plain meaning," "deterring" would still not be "killing," as alleged by the Office. Applicants note that "plain meaning" refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art. *Id.* In the relevant art, insect deterrents or repellents are typically those that only repel or otherwise deter an insect from biting or landing on an animal. It is widely understood that these deterrents, e.g., DEET, generally do not effectively kill insects or other parasites. Further, it is generally understood in the relevant art that pesticides, acaricides, and other insecticides are known to kill and combat insects and parasites, but not to deter them or prevent them from landing on plants or animals without killing them. Accordingly, in the relevant art, the terms kill and deter are distinctly defined.

The Office alleges that since Willis allegedly teaches use of the same compound for combating ticks, the deterring effect necessarily occurs. Final Office Action at 4. Applicants respectfully note that, at most, Willis teaches that a haloarylpyrazole can be used as an insecticide or acaricide, but does not teach that the haloarylpyrazole repels or effectively deters ticks in accordance with applicants' claimed methods. Further, "[t]he discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using." *In re Hack*, 114 USPQ 161,163 (CCPA 1957).

In the instant case, while Willis may teach haloarylpypyrazoles can be used as an insecticide or acaricide, applicants' research discovered that the claimed methods can be used in deterring or repelling ticks, as presently claimed.

In view of the foregoing, Willis does not disclose or describe a method for deterring ticks from infesting an animal that was previously uninfested, as presently claimed. Reconsideration and withdrawal of the 35 U.S.C. § 102 rejections are respectfully requested.

35 U.S.C. § 103

Claims 1-10 and 13-19 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent 5,189,053 to Willis ("Willis"). Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) **must teach or suggest all the claim elements**. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Additionally, there must have been "a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Furthermore, to establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Finally, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006); MPEP § 2144.

Applicants submit that in view of the amendments and remarks presented herein, and those remarks presented in the Response submitted June 1, 2009, which remarks are incorporated by reference herein, claims 1-10 and 13-19 are not obvious over Willis.

The mere fact that references can be modified does not render the resultant modification obvious unless the results would have been predictable to one of ordinary skill in the art. MPEP § 2143.01(III); *KSR International Co.*, 82 USPQ2d at 1396. The relevant art and the reference

relied upon by the Office do not teach or suggest that the haloarylpyrazole compounds of the claimed methods can be used to “deter,” or prevent ticks from biting or attaching as presently defined in the claims.

As previously discussed, the teachings of Willis at most suggest that haloarylpyrazole compounds can be effective as insecticides and acaricides. A person of ordinary skill in the art would not have known, nor would he or she have expected that a compound having insecticidal or acaricidal effects would have been able to “deter,” or otherwise repel a parasite, as presently claimed. Indeed, as previously discussed, most insecticidal and acaricidal compounds do not have a deterrent effect, while some other compounds (e.g., DEET) have a deterrent effect or are repellent, but are not effective insecticides and acaricides. Accordingly, a person of ordinary skill in the art would not have been able to reasonably predict or expect that the haloarylpyrazole compounds taught in Willis would have had been effective as a deterrent or repellent, as presently claimed.

In view of the fact that it would not have been reasonably predicted or otherwise expected in the art that the haloarylpyrazole compounds taught in Willis would have been effective as a deterrent or repellent, as claimed, a person of ordinary skill in the art would not have been motivated to administer haloarylpyrazole compounds as a deterrent in accordance with the present claims. As such, applicants submit that amended claims 1-10 and 13-19 are not obvious over Willis.

Standards for Unpredictability and Unexpected Results are based upon Understanding and Knowledge in the Art Prior to Applicants' priority date.

Even if the Office had established *prima facie* obviousness for claims 1-10 and 13-19, which applicants dispute herein, the currently presented claims are not obvious as applicants' claimed methods for deterring tick infestations on previously uninfested animals was unexpected prior to applicants' priority date. Whether a function, characteristic, property, etc. is predictable or unexpected is based upon the understanding and knowledge in the art prior to an applicant's priority date.

As previously set forth, the prior art when considered as whole suggests that haloarylpyrazole compounds can be effective as insecticides and acaricides. This, in conjunction

with the general understanding in the art prior to applicant's invention that most insecticidal and acaricidal compounds do not have a deterrent effect, at the very least suggests that a person of ordinary skill in the art would not have expected that the haloarylpyrazole compounds in Willis would have had a "deterrent effect," as presently claimed.

As previously discussed, the claims recite a new use for the compounds of Formula I and such use exhibits unexpected properties. While a new use for an otherwise obvious composition cannot render a claim to the composition patentable, any unexpected results accompanying a method including the new use leads to patentable subject matter. *In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007).

Applicants submit that in view of the foregoing, claims 1-10 and 13-19 are not obvious over Willis. Reconsideration and withdrawal of the 35 U.S.C. § 103 rejections are respectfully requested.

Claims 7, 8, 14, and 16

As remarked in the previous response, claims 7, 8, 14, and 16 are further not obvious because Willis does not teach or suggest an initial dosage of 4 mg/kg bodyweight of the animal followed by weekly administration of doses of 2 mg/kg bodyweight of the animal. Instead, Willis administers a dosage of 100 mg/kg of bodyweight of the animal in order to kill an endoparasite. However, the compounds of claims 7, 8, 14, and 16 are used at much lower dosages to "deter" infestation of an ectoparasite. The Office argues that it would have been *prima facie* obvious to one of ordinary skill in the art...to optimize dosage of the compound for each animal based on the severity of the infestation. Final Office Action at page 9. However, Willis provides no guidance regarding the dosage requirement for deterring a tick infestation. As such, Willis does not teach a value that may be "optimized" since Willis neither attempts to deter infestations, let alone tick infestations.

Applicants additionally submit that, the unexpected "deterring" effect of the claimed dosages, as previously described, indicate that it would not have been obvious to optimize the dosages of the haloarylpyrazole compounds in Willis. Indeed,

"[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the

optimum or workable ranges of said variable might be characterized as routine experimentation.”

MPEP § 2144.05 (II)(B) citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) emphasis added.

In the instant case, the reference relied upon by the Office, to wit, Willis, does not teach that a “deterrent effect” in accordance with the claimed methods would have been a recognized result, or a result effective variable. Indeed, the evidence of record and the general understanding in the art suggests the opposite, *e.g.*, that most insecticidal and acaricidal compounds do not have a deterrent effect, while some other compounds (*e.g.*, DEET) have a deterrent effect or are repellent, but are not effective insecticides and acaricides.

The Office alleges that the “active ingredient” is clearly a result-effective variable. Final Office Action at 9. Applicants respectfully submit that while the active ingredient may be disclosed in Willis, the result-effective variable of the instant claims is a “deterring effect” that is clearly not predictable based on Willis, as Willis at most suggests the active ingredient is effective in killing.

In view of the fact that the “deterrent effect” using the claimed dosages would not have been recognizable to those in the art, it would not have been obvious to optimize the dosage levels taught in Willis in accordance with claims 7, 8, 14, and 16. Accordingly, reconsideration and withdrawal of the 35 U.S.C. §103 rejections of claims 7, 8, 14, and 16 are respectfully requested.

Double Patenting

Claims 1-20 are provisionally rejected on grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 5-18 of co-pending Application No. 11/698,683 (hereinafter ‘683). Applicants note that ‘683 was filed after the instant application. The MPEP states that

“if a ‘provisional’ nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.” *See*, MPEP § 804(I)(B)(1), page

800-17.

Accordingly, applicants respectfully request that the Office hold the provisional rejection in abeyance, and then withdraw the provisional rejection once it is the only rejection remaining in instant application.

Claims 1-20 are provisionally rejected on grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 6-11 and 19-20 of co-pending Application No. 10/577,232 (hereinafter ‘232). Applicants respectfully note that ‘232 and the instant application were filed on the same day, April 26, 2006. In such a case, MPEP § 804 states that

“[i]f both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.”

See, MPEP § 804(I)(B)(1), page 800-17.

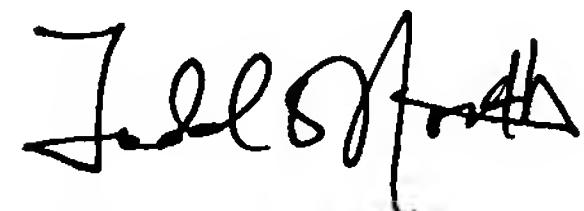
In view of MPEP § 804, it is respectfully requested that the Office hold the provisional rejection in abeyance pending the Office’s determination of which application claims the base invention and which application claims the improvement.

Entry of Amendments

The amendments to claims 1-2, 8-9, 11-12, 14, and 20 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search, as the issues have been previously discussed and claimed.

Claims 1-20 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants’ undersigned attorney.

Respectfully submitted,



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